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Application No.: 10/762,880
Notice of Allowance Dated: November 2, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bruce A. Williams and Joseph Kaminski

Confirmation No.: 5450

Application No.: 10/762,880

Group Art Unit: 3736

Filing Date: January 22, 2004

Examiner: Michael C. Astorino

For: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Dug May Be Contraindicated

DATE OF DEPOSIT: February 2, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

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Sir:

Comments on Statement of Reasons for Allowance

Applicants wish to thank the Examiner for the Notice of Allowance dated November 2, 2004, indicating that claims 1-19 are allowed. Applicants are aware that the examiner's statement of reasons for allowance is the personal opinion of the examiner as to why the claims are allowable, and should not create an estoppel. M.P.E.P. §1302.14. Furthermore, although failure of Applicants to comment on the examiner's statement of reasons of allowance should not be treated as acquiescence to the examiner's statement, Applicants submit the following comments in response to the examiner's statement of reasons for

allowance.

According to the Examiner, Schauss et al. and Boyer et al. allegedly disclose various aspects of the applicants claimed invention. Applicants traverse this assertion. Applicants' invention encompasses, *inter alia*, a method for treating erythema nodosum leprosum using thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has received an approval code for the prescription from a computer readable storage medium, wherein generation of the prescription approval code comprises the following steps: defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide; defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient; in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium; based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and upon a determination that the risk is acceptable, generating the prescription approval code to be received by the pharmacy before the prescription is filled. Both Schauss et al. and Boyer et al. fail to disclose Applicants' invention.

Contrary to the Examiner's assertions, Schauss et al. does not teach Applicants' invention. Schauss et al. fails to disclose, *inter alia*, defining a set of information to be obtained by a patient which is probative of the risk of an adverse side effect, and registering patients, physicians and pharmacies in a computer medium for the distribution of a drug which is contraindicated. Likewise, Boyer et al. does not teach, *inter alia*, defining a

plurality of risk groups based on predefined risk parameters, defining a set of information to be obtained by a patient which is probative of the risk of an adverse side effect, and registering patients, physicians and pharmacies in a computer medium for the distribution of a drug which is contraindicated.

Date: 2/2/05

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